

PATENT

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APPLICATION FOR UNITED STATES LETTERS PATENT

for

AN EPIDURAL CATHETER DISPENSER SYSTEM TO CONTAIN AND
CONTROL AN EPIDURAL CATHETER, MAINTAIN EPIDURAL
CATHETER STERILITY AND PREVENT EPIDURAL CATHETER
CONTAMINATION

by

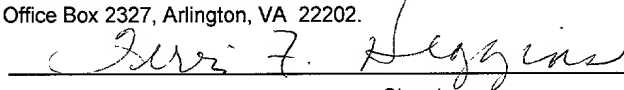
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BACKGROUND OF THE INVENTION

An epidural injection is a medical anesthetic technique whereby medication, typically an anesthetic agent with or without a steroidal component, is administered to a patient's spine, specifically in the epidural space. The epidural space consists of the space between a patient's bony spinal vertebrae and the dura mater, or tough outer layer of the spinal cord. Epidural injections are most commonly used to alleviate pain associated with childbirth or nerve root impingement. Nerve roots are bands of nerves extending from the spinal cord in the vertebral canal to the body through intervertebral foramina, or spaces between vertebrae. Nerve roots can become impinged as a result of a bulging, herniated or ruptured intervertebral disc due to compression or wear. Nerve root impingement can also occur as a result of a radiculopathy, bony osteophyte or projection compressing the nerve root.

For the administration of an epidural injection, a physician will request the patient to lie in a fetal position, whereby the patient's knees are pulled closely to her chest. This creates a convex curvature for the patient's spine, resulting in the widening of the intervertebral space between each vertebra's spinous process. The physician may then palpate the intervertebral space at the level of the spine in which the epidural injection is desired to be administered to alleviate pain.

After locating the precise point to administer the epidural injection, the physician will use an aseptic technique to prep and drape the area and cleanse the area of bacteria to prevent infection. During the prep and drape process, the physician will use iodine and a brush to scrub the skin surface several times. The physician will also drape the local area with sterile cloths, leaving only the small area to administer the epidural uncovered.

To administer the actual epidural injection the physician will use a sterile, pre-packaged epidural kit containing an epidural needle with a proximal end containing the handle and a distal end that is inserted into the patient. Within the epidural needle's hollow bore is a plunger with a proximal end containing a handle and a distal end that extends into the needle. The epidural needle with its corresponding plunger can vary in length and gauge, or diameter of the hollow bore, depending on the size of the patient. The sterile epidural kit also contains coiled, sterile, flexible catheter tubing, which at the appropriate time is inserted into the epidural needle and directed into the patient's

1 epidural space at various lengths to carry the anesthetic medication into the epidural
2 location.

3 When administering the epidural injection, the physician, with sterile gloves, will
4 use a local anesthetic, such as lidocaine, on the skin and surface tissue to prevent surface
5 pain from the injection. The physician will then insert the epidural needle into the patient
6 to the epidural space. The physician will then slowly withdraw the plunger in the
7 epidural needle, observing for any backflash. Bloody backflash may indicate the
8 puncture of a vein, or a pulsating backflash of blood may indicate the puncture of an
9 artery. In either scenario, the practitioner may have to readjust the epidural needle and
10 monitor the backflash after removing the plunger.

11 With satisfactory placement of the epidural needle and removal of the intra-needle
12 plunger, the physician will then remove the sterile catheter tubing from the pre-packaged
13 epidural kit and slowly insert one end of the catheter (also known as the catheter's distal
14 end) into the hollow bore of the needle positioned in the patient. The catheter is then
15 advanced in the needle into the patient until the desired length of catheter insertion is
16 achieved. At this point, to remove the epidural needle and leave only the catheter in the
17 patient, the physician firmly secures the catheter in the patient with one hand, while
18 simultaneously withdrawing the needle away from the patient with the other hand. With
19 the withdrawal of the needle, the entire catheter passes through the hollow bore of the
20 epidural needle. When the needle has been successfully removed from the patient
21 through the entire length of the catheter tubing, the proximal end of the catheter (e.g. the
22 catheter end not inside the patient) is ready to receive the medication for introduction into
23 the patient. The catheter can be immediately withdrawn from the patient after medication
24 is administered, or the catheter can be left in the patient as an in-dwelling catheter for
25 extended periods of medication administration.

26 As a modestly invasive procedure, an epidural injection can have adverse effects,
27 one of which is infection. Infection from an epidural procedure can manifest as an
28 epidural abscess or, in severe cases, bacterial meningitis, an infection of the meninges of
29 the central nervous system. Curative measures for an epidural abscess can require
30 surgical drainage, while bacterial meningitis may require extensive antibiotics and
31 significant hospitalization.

1 Ruling out blood-borne sources of infection from the patient, a primary source of
2 infection for an epidural injection is manifest in the procedure itself. A contributing
3 factor influencing the likelihood of infection from the procedure is the narrow sterile field
4 in which the procedure occurs, as defined by the area on the patient that the physician
5 prepped and draped. Any contaminants outside this narrow sterile field can potentially
6 enter the field and provide a source for infection. The most significant factor
7 contributing to the likelihood of infection from an epidural injection is the free, proximal
8 end of the catheter that is dangling freely as the catheter's distal end is inserted into the
9 epidural needle and into the patient. Because the catheter is packaged in a coiled form,
10 upon unraveling for use, the lengthy catheter tubing is very difficult to manage and
11 control as it is being inserted into the patient's epidural space. The difficulty in
12 controlling the free end of the catheter is further compounded by the inability of the
13 physician to utilize both hands to manipulate the catheter. Because the practitioner must
14 keep one hand holding the needle in the patient, the practitioner can only utilize the other
15 hand to control the catheter tubing's free proximal end while simultaneously trying to
16 maneuver the distal, inserted end of the catheter. Furthermore, during the needle
17 removal process after the catheter has been introduced into the patient, the needle must be
18 removed while passing the entire catheter through the needle's bore which poses
19 additional opportunity to lose control of the catheter. The practitioner is limited in the
20 ability to keep the catheter inside the patient, remove the needle and control the free-
21 hanging portion of the catheter.

22 In consideration of these factors involved during the procedure, the risk of the
23 catheter springing out of the physician's hand can be high and the catheter may
24 subsequently contact areas outside the sterile field, thus breaking the narrow, sterile field
25 and potentially introducing contaminants. In the event control of the catheter is lost and
26 the catheter has become contaminated, prior to insertion, the practitioner must discard the
27 contaminated catheter and re-introduce a new, sterile catheter. In the event the catheter
28 has been inserted into the patient and the distal end breaches the sterile field, the
29 practitioner must either wipe down the compromised end with alcohol or sever the
30 affected end from the catheter before continuing with the procedure. In this likely
31 scenario, many negative outcomes are produced, including: (1) wasted medical resources

1 in time, supplies and money; (2) additional likelihood of patient infection due to the
2 increased time the patient's closed body system is exposed to the environment; and (3)
3 the loss of the practitioner's ability to respond and control the medical microenvironment
4 while having both hands occupied.

5 The medical necessity of administering epidural medicaments to alleviate pain or
6 deliver other beneficial medications to the epidural space remains. However, in light of
7 the inherent faults of the epidural injection procedure for potential patient infections,
8 there exists no replacement procedure to eliminate the infection potential, specifically
9 addressing the lack of control over the free-hanging, proximal end of the catheter.
10 Additionally, no current medical device technology attempts to eliminate the lack of
11 control over the free-hanging, proximal end of the catheter to address the issue of
12 potential infection for epidural injections and catheter insertion. Thus, there exists in the
13 medical procedure for epidural injections a need to eliminate the inability of the
14 physician to control the proximal, free-hanging end of the catheter tubing to avoid
15 contamination during insertion of the catheter in the needle bore and during the removal
16 of the needle from the patient's body while pulling the catheter through the needle's bore.

18 SUMMARY OF THE INVENTION

19 The epidural catheter dispenser system of the current invention addresses the
20 shortcomings of current medical practice to prevent infection during the epidural
21 injection procedure. The current invention's dispenser system includes a cylindrical
22 dispenser with a rounded, conical top, all of which is made from rigid or semi-rigid
23 material, most preferably plastic. The conical top of the current invention's dispenser
24 contains a small aperture that provides a conduit between the dispenser's inner cavity and
25 the casing's exterior. On the bottom of the current invention's dispenser, a larger
26 aperture exists that provides a conduit between the dispenser's inner cavity and the
27 casing's exterior.

28 The current invention's dispenser surrounds an inner cavity, providing a hollow
29 interior for the epidural catheter dispenser system. The system of the current invention
30 involves the "loading" of an epidural catheter of variable length coiled inside the current
31 invention's inner cavity through the aperture on the dispenser's bottom side. With the

1 catheter's placement in the inner cavity of the current invention, a distal end of the
2 catheter is threaded through the aperture on the dispenser's conical top, thus leaving the
3 proximal end of the catheter in a controlled, contained environment. The epidural
4 catheter dispenser system of the current invention is now prepared for use by a physician.

5 In practical usage for epidural injections, the current invention's epidural catheter
6 dispenser system is placed in either one of the physician's hands after the epidural needle
7 has been satisfactorily placed in the patient's back. With one hand holding the epidural
8 needle in place and the other hand holding the epidural catheter dispenser system, the
9 physician will cup the current invention's dispenser with the third, fourth, and fifth digits
10 of her hand, leaving the thumb and index finger free to manipulate the catheter. Grasping
11 the distal end of the coiled catheter, which was previously threaded through the aperture
12 on the dispenser's conical top from the inner cavity, with her free thumb and index
13 finger, the physician then directs the catheter's distal end to the central bore of the
14 epidural needle. With successful introduction of the catheter into the epidural needle, the
15 physician can manually advance the catheter to the desired length into the epidural needle
16 and into the patient with her thumb and index finger while simultaneously controlling the
17 epidural catheter dispensing system in the palm of the same hand with her third, fourth,
18 and fifth digits.

19 After the catheter has been advanced from the epidural catheter dispensing system
20 of the current invention to the desired length inside the patient's epidural space, the
21 physician may remove the epidural needle safely and effectively using the epidural
22 catheter dispensing system. To remove the epidural needle from the patient, the epidural
23 needle is withdrawn by the practitioner's hand not holding the dispenser system of the
24 current invention. Once the epidural needle has been completely withdrawn from the
25 patient's skin and soft tissue, the base of the needle is transferred to the thumb and index
26 finger, or alternatively to the index finger and the third digit, of the practitioner's hand
27 holding the epidural catheter dispensing system of the current invention. The
28 practitioner's hand originally holding the epidural needle is now transferred to hold the
29 area of the catheter immediately adjacent to the patient's skin where the catheter enters
30 the patient's back. Securing the catheter firmly next to the patient's skin, the practitioner
31 can completely withdraw the epidural needle with the catheter running through the

1 needle's bore by simultaneously pulling the epidural needle and the epidural catheter
2 dispensing system of the current invention back with the same hand such that the epidural
3 needle runs the entire length of the remaining catheter in the inner cavity of the current
4 invention's dispenser up to the catheter's proximal end. Thus, during the needle
5 withdrawal procedure, the physician – with one hand – would have maneuvered the entire
6 length of catheter through the epidural needle's bore.

7 Concerning the entire procedure of administering an epidural injection, the unique
8 advantages of the epidural catheter dispensing system are appropriate and desirable. By
9 placing the catheter's proximal end in a controlled, closed and sterile dispenser, the
10 epidural catheter dispensing system of the current invention eliminates the catheter's
11 freely-hanging proximal end in traditional procedures, thus eliminating any likelihood of
12 contaminating the catheter as a source for possible infection. Without having to contend
13 with a freely-hanging proximal end of a catheter, any physician using the current
14 invention's epidural catheter dispensing system can better command and maneuver the
15 catheter and epidural needle during the procedure to maintain control of the medical
16 environment. Additionally, the physician does not have to concern herself with the
17 possibility of the catheter breaking the sterile field, thus allowing the practitioner to
18 concentrate more fully on the patient and the epidural injection procedure.

19 The current invention's epidural catheter dispensing system is also
20 socioeconomically desirable. Because the current invention's epidural catheter
21 dispensing system offers a reduced likelihood of infection risk from epidural injections,
22 patient satisfaction and morbidity will likely improve following such procedure; and
23 therefore, the amount of medical malpractice litigation stemming from or involving such
24 procedure will likely decrease proportionately. Extending this societal benefit further,
25 from a products liability standpoint, manufacturers of epidural products and catheters
26 would likely experience decreased liability with the addition of the epidural catheter
27 dispensing system of the current invention because of the benefits in infection control.
28 Alternatively, patients who are subjected to an epidural injection with a catheter not
29 having the current invention's epidural catheter dispensing system and who experience ill
30 effects from such procedure, specifically infection, may recover damages from
31 manufacturers who are aware of the current invention's dispensing system but who

1 choose not to include the current invention in their epidural injection products package.
2 Thus, the current invention's epidural catheter dispensing system is desirable for patients
3 and product manufacturers.

4 No current medical technology has addressed the problems with catheter
5 contamination contributing to infection inherent in current epidural injection procedure,
6 especially in a handheld device or system sterilely containing the catheter that the
7 physician may manipulate in one hand. A technology system does exist for a handheld
8 storage system for guidewires used in catheter exchange procedures primarily in
9 cardiology and angioplasty procedures; however, no similar technology has been
10 adapted for the use of catheters in epidural injection procedures. That the handheld
11 guidewire technology has not been adapted for the use of epidural catheters in epidural
12 injection procedures illustrates the difference in application and technologies between a
13 handheld guidewire storage system and the epidural catheter dispenser system of the
14 current invention. For example, both technologies are used in vastly different procedures
15 - the guidewire is used primarily as an internal placement and guidance device for
16 catheters inside patients and used in procedures where the physician may insert and
17 withdraw many different catheters of varying gauges or configurations from the patient (a
18 procedure known as catheter exchange). Contrastingly, catheters are used as the primary
19 conduit into a patient's body to administer medications or take internal body readings.
20 Thus, catheters and guidewires functionally serve vastly different medical purposes, and
21 no current medical device exists addressing the prevention of catheter contamination in a
22 handheld device.

23 Catheters and guidewires characteristically differ such that the adaptation of the
24 handheld guidewire storage device to the epidural catheter for epidural injections would
25 be impractical. Guidewires used in cardiology and catheter exchange procedures vary in
26 length from 190-400 cm and are made of a solid rigid metallic material, likely stainless
27 steel. Because guidewires are solid and made of a rigid metallic material, the guidewires'
28 elastic properties are resilient; however, the guidewires' thin gauge to navigate the human
29 vasculature makes the guidewires susceptible to kinking. In contrast, epidural catheters
30 are hollow tubes of impermeable plastic typically less than 100 cm in length. The plastic
31 properties allow the epidural catheter's elasticity to be extremely flexible; and the

1 epidural catheter's hollow gauge, larger than that of the solid guidewire, makes the
2 epidural catheter less susceptible to kinking. Thus, in light of the differences between
3 guidewire properties and epidural catheter properties, a handheld storage device for
4 guidewires would be impractical for use with epidural catheters without improvements
5 and adaptations in the device as applied to use with the epidural injection procedure
6 intended and the epidural catheter materials used.

7 8 **BRIEF DESCRIPTION OF THE DRAWINGS**

9 FIGURE 1A is a lateral view of the epidural catheter dispenser system with an
10 epidural catheter.

11 FIGURE 1B is an aerial view of the epidural catheter dispenser system with an
12 epidural catheter.

13 FIGURE 1C is a lateral view of the epidural catheter dispenser system without an
14 epidural catheter.

15 FIGURE 1D is an angled view of the epidural catheter dispenser system without
16 an epidural catheter.

17 FIGURE 2 is an epidural needle.

18 FIGURE 3 illustrates proper handling and positioning of an epidural needle.

19 FIGURE 4 illustrates the insertion of an epidural needle into a patient.

20 FIGURE 5 illustrates the introduction of the epidural catheter dispenser system to
21 the epidural injection procedure.

22 FIGURE 6 illustrates the insertion of the distal epidural catheter end into the
23 epidural needle bore.

24 FIGURE 7 illustrates the successful insertion of the distal epidural catheter end
25 into the patient's epidural space.

26 FIGURE 8 illustrates early-staged withdrawal of the epidural needle from the
27 patient.

28 FIGURE 9 illustrates the continued removal of the epidural needle from the
29 patient.

1 FIGURE 10 illustrates the completed removal of the epidural needle from the
2 patient and successful completion of the epidural catheter placement in the patient's
3 epidural space.

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2715281529153015311532153315341535153615371538153915401541154215431544154515461547154815491550155115521553155415551556155715581559156015611562156315641565156615671568156915701571157215731574157515761577157815791580158115821583158415851586158715881589159015911592159315941595159615971598159916001601160216031604160516061607160816091610161116121613161416151616161716181619162016211622162316241625162616271628162916301631163216331634163516361637163816391640164116421643164416451646164716481649165016511652165316541655165616571658165916601661166216631664166516661667166816691670167116721673167416751676167716781679168016811682168316841685168616871688168916901691169216931694169516961697169816991700170117021703170417051706170717081709171017111712171317141715171617171718171917201721172217231724172517261727172817291730173117321733173417351736173717381739174017411742174317441745174617471748174917501751175217531754175517561757175817591760176117621763176417651766176717681769177017711772177317741775177617771778177917801781178217831784178517861787178817891790179117921793179417951796179717981799180018011802180318041805180618071808180918101811181218131814181518161817181818191820182118221823182418251826182718281829183018311832183318341835183618371838183918401841184218431844184518461847184818491850185118521853185418551856185718581859186018611862186318641865186618671868186918701871187218731874187518761877187818791880188118821883188418851886188718881889189018911892189318941895189618971898189919001901190219031904190519061907190819091910191119121913191419151916191719181919192019211922192319241925192619271928192919301931193219331934193519361937193819391940194119421943194419451946194719481949195019511952195319541955195619571958195919601961196219631964196519661967196819691970197119721973197419751976197719781979198019811982198319841985198619871988198919901991199219931994199519961997199819992000200120022003200420052006200720082009201020112012201320142015201620172018201920202021202220232024202520262027202820292030203120322033203420352036203720382039204020412042204320442045204620472048204920502051205220532054205520562057205820592060206120622063206420652066206720682069207020712072207320742075207620772078207920802081208220832084208520862087208820892090209120922093209420952096209720982099210021012102210321042105210621072108210921102111211221132114211521162117211821192120212121222123212421252126212721282129213021312132213321342135213621372138213921402141214221432144214521462147214821492150215121522153215421552156215721582159216021612162216321642165216621672168216921702171217221732174217521762177217821792180218121822183218421852186218721882189219021912192219321942195219621972198219922002201220222032204220522062207220822092210221122122213221422152216221722182219222022212222222322242225222622272228222922302231223222332234223522362237223822392240224122422243224422452246224722482249225022512252225322542255225622572258225922602261226222632264226522662267226822692270227122722273227422752276227722782279228022812282228322842285228622872288228922902291229222932294229522962297229822992300230123022303230423052306230723082309231023112312231323142315231623172318231923202321232223232324232523262327232823292330233123322333233423352336233723382339234023412342234323442345234623472348234923502351235223532354235523562357235823592360236123622363236423652366236723682369237023712372237323742375237623772378237923802381238223832384238523862387238823892390239123922393239423952396239723982399240024012402240324042405240624072408240924102411241224132414241524162417241824192420242124222423242424252426242724282429243024312432243324342435243624372438243924402441244224432444244524462447244824492450245124522453245424552456245724582459246024612462246324642465246624672468246924702471247224732474247524762477247824792480248124822483248424852486248724882489249024912492249324942495249624972498249925002501250225032504250525062507250825092510251125122513251425152516251725182519252025212522252325242525252625272528252925302531253225332534253525362537253825392540254125422543254425452546254725482549255025512552255325542555255625572558255925602561256225632564256525662567256825692570257125722573257425752576257725782579258025812582258325842585258625872588258925902591259225932594259525962597259825992600260126022603260426052606260726082609261026112612261326142615261626172618261926202621262226232624262526262627262826292630263126322633263426352636263726382639264026412642264326442645264626472648264926502651265226532654265526562657265826592660266126622663266426652666266726682669267026712672267326742675267626772678267926802681268226832684268526862687268826892690269126922693269426952696269726982699270027012702270327042705270627072708270927102711271227132714271527162717271827192720272127222723272427252726272727282729273027312732273327342735273627372738273927402741274227432744274527462747274827492750275127522753275427552756275727582759276027612762276327642765276627672768276927702771277227732774277527762777277827792780278127822783278427852786278727882789279027912792279327942795279627972798279928002801280228032804280528062807280828092810281128122813281428152816281728182819282028212822282328242825282628272828282928302831283228332834283528362837283828392840284128422843284428452846284728482849285028512852285328542855285628572858285928602861286228632864286528662867286828692870287128722873287428752876287728782879288028812882288328842885288628872888288928902891289228932894289528962897289828992900290129022903290429052906290729082909291029112912291329142915291629172918291929202921292229232924292529262927292829292930293129322933293429352936293729382939294029412942294329442945294629472948294929502951295229532954295529562957295829592960296129622963296429652966296729682969297029712972297329742975297629772978297929802981298229832984298529862987298829892990299129922993299429952996299729982999300030013002300330043005300630073008300930103011301230133014301530163017301830193020302130223023302430253026302730283029303030313032303330343035303630373038303930403041304230433044304530463047304830493050305130523053305430553056305730583059306030613062306330643065306630673068306930703071307230733074307530763077307830793080308130823083308430853086308730883089309030913092309330943095309630973098309931003101310231033104310531063107310831093110311131123113311431153116311731183119312031213122312331243125312631273128312931303131313231333134313531363137313831393140314131423143314431453146314731483149315031513152315331543155315631573158315931603161316231633164316531663167316831693170317131723173317431753176317731783179318031813182318331843185318631873188318931903191319231933194319531963197319831993200320132023203320432053206320732083209321032113212321332143215321632173218321932203221322232233223432253226322732283229323032313232323332343235323632373238323932403241324232433244324532463247324832493250325132523253325432553256325732583259326032613262326332643265326632673268326932703271327232733274327532763277327832793280328132823283328432853286328732883289329032913292329332943295329632973298329933003301330233033304330533063307330833093310331133123313331433153316331733183319332033213322332333243325332633273328332933303331333233333334333533363337333833393340334133423343334433453346334

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

FIGURE 1A illustrates a lateral view of a preferred embodiment for the epidural catheter dispenser system with an epidural catheter. The catheter tubing 1 is shown with a portion of the catheter outside the dispenser and with the remaining portion of the catheter wound inside the dispenser's inner cavity 5. Preferably, and to prevent tangling, the catheter is wound flat against the bottom of the dispenser. The dispenser's inner cavity 5 is defined in the preferred embodiment by the sidewall 2 which can take a cylindrical shape, as illustrated, or a conical or other polyhedral shape. In some embodiments, the dispenser may have a spherical or cubic shape. The proximal end piece 3 defines the bottom border of the inner cavity 5 and the distal end piece 4 defines the upper border of the inner cavity. While not visible from the lateral view of FIGURE 1A, a dispenser aperture 6 on the distal end piece 4 allows the catheter 1 to pass through from the inner cavity 5 to the exterior environment.

FIGURE 1B illustrates an aerial view of the preferred embodiment for the epidural catheter dispenser system. The catheter 1 is again illustrated as wound in the dispenser's inner cavity, as defined by the sidewall 2. The catheter exits the inner cavity via the dispenser aperture 6 on the distal end piece of the current invention's preferred embodiment. A loading aperture 7 located on the proximal end piece allows for the loading or adjusting of the catheter into the inner cavity of the dispenser.

FIGURE 1C illustrates a lateral view of the preferred embodiment of the epidural catheter dispenser system without the loaded epidural catheter. There exists in the preferred embodiment a sidewall 2 connected to a proximal end piece 3 which forms the dispenser's bottom, and a distal end piece 4 which forms the dispenser's top. The sidewall and proximal and distal end pieces define an inner cavity 5 where the sterile epidural catheter is loaded for use. The sterile inner cavity 5 maintains the sterile environment for which the epidural catheter is contained during the epidural catheter placement in an epidural injection procedure, reducing the likelihood of catheter contamination and patient infection.

FIGURE 1D illustrates an angled view of the epidural catheter dispenser system's preferred embodiment without a loaded epidural catheter. The dispenser's preferred embodiment includes a sidewall 2 connected to a proximal and a distal end piece 3 and 4,

1 respectively, thus forming a sterile inner cavity 5 where the epidural catheter is
2 contained. Although the sidewall is illustrated taking a cylindrical form, the sidewall
3 may also include other forms such as a conical shape or other polyhedral shape. An
4 epidural catheter is loaded into the dispenser's inner cavity through a loading aperture 7
5 located and defined on the proximal end piece 3. During the epidural catheter placement
6 procedure in a patient, the catheter is extracted from the inner cavity 5 for use through the
7 dispenser aperture 6 located and defined on the distal end piece 4. Because the sterile
8 epidural catheter is controlled and contained in a sterile environment throughout the
9 epidural catheter placement portion of the procedure, the preferred embodiment of the
10 current invention reduces the likelihood of catheter contamination and possible patient
11 infection.

12 FIGURE 2 illustrates an epidural needle 8 which although not part of the
13 preferred embodiment of the current invention, serves to illustrate the preferred use of the
14 epidural catheter dispensing system of the current invention. The distal end of the
15 epidural needle is the tip, which is inserted into the patient to the patient's epidural space.
16 The proximal end of the epidural needle 10 is the needle's handle the physician uses to
17 control the epidural needle. Coursing the entire length of the epidural needle 8 from the
18 handle to the needle tip is a hollow bore 11 through which the needle plunger 9 is
19 inserted as well as the epidural catheter once the needle plunger 9 has been removed
20 during an epidural injection procedure. The needle plunger 9 is utilized during the
21 epidural procedure to determine whether the physician has punctured any vasculature.
22 By withdrawing the needle plunger 9 and observing the coloration of any backflash fluids
23 coming through the epidural needle bore 11 the physician can better determine the
24 location of the distal end of the needle inside the patient. With satisfactory placement of
25 the epidural needle 8 the physician will completely withdraw the needle plunger, 9, from
26 the epidural needle bore 11 allowing for the insertion of the epidural catheter. FIGURE 3
27 illustrates the proper handling of an epidural needle 8 in the physician's hand 12. The
28 epidural needle 8 can be used in either of the physician's hands, but as illustrated, the
29 epidural needle 8 is in the physician's left hand 12. The proper handling of the epidural
30 needle 8 is such that the physician has the epidural needle handle positioned between the

1 thumb and index finger for maximum control and dexterity in maneuvering the needle to
2 the appropriate position on the and in the patient.

3 FIGURES 4 through 10 illustrate the preferred method of use for the preferred
4 embodiment of the current invention's epidural catheter dispenser system and how the
5 current invention is used to place an epidural catheter in conducting an epidural injection
6 procedure. Referring to FIGURE 4, the illustration shows the introduction of the epidural
7 needle 8 into the patient's body 14 specifically at the location between the vertebral
8 spinous processes 15 also known as the intervertebral space 16. The physician inserts the
9 epidural needle 8 into the patient 14 until the distal end of the needle has reached the
10 epidural space. With satisfactory placement of the epidural needle 8 the physician will
11 withdraw the needle plunger completely if no bloody flashback is observed through the
12 epidural needle bore. The physician's left hand 12 is illustrated properly manipulating
13 the epidural needle 8 between the thumb and index finger.

14 FIGURE 5 illustrates the introduction of the epidural catheter dispensing system
15 of the current invention to the epidural injection procedure. The physician has already
16 successfully placed the epidural needle 8 into the patient 14 at the desired location. The
17 physician has also completely removed the needle plunger from the epidural needle bore.
18 The epidural needle 8 is now prepared to receive the epidural catheter 1 for introduction
19 into the patient's epidural space. As FIGURE 5 illustrates, the physician, while holding
20 the epidural needle 8 in the patient's back with the left hand 12 has now grasped the
21 epidural catheter dispensing system 18 into the right hand 17. The dispenser 18 is
22 positioned in the physician's righthand palm 17 and is secured with the third, fourth, and
23 fifth digits. The physician has also grasped the distal catheter end 19 with the thumb and
24 index fingers of the right hand and has positioned the distal catheter end 19 for insertion
25 into the epidural needle bore. The remainder of the epidural catheter 1 and the proximal
26 end of the catheter 20 stay contained and controlled in the sterile environment of the
27 dispenser's inner cavity, avoiding any possibility of contamination.

28 FIGURE 6 illustrates the successful insertion of the distal epidural catheter end 19
29 into the epidural needle bore. The physician is still maintaining control of the epidural
30 needle 8 in the patient 14 with the thumb and index finger of the left hand 12. The
31 physician still has control over the epidural catheter dispensing system 18 in the palm of

the right hand 17 secured with the third, fourth, and fifth digits. As illustrated, the epidural catheter 1 and its proximal end are clearly confined in the inner cavity 5 of the epidural catheter dispenser system such that there is no likelihood for the catheter to become contaminated as a possible source of infection. The physician at the stage illustrated in FIGURE 6 will advance the distal epidural catheter end 19 the entire length of the epidural needle 8 into the patient's epidural space.

FIGURE 7 illustrates that the physician has utilized the epidural catheter dispensing system 18 to successfully introduce the distal catheter end 19 into the patient's body and epidural space 14. Although the distal catheter end 19 is in the patient, a portion of the epidural catheter 1 is in the epidural needle 13 bore with the remainder, including the proximal catheter end, still in the epidural catheter dispensing system 18, specifically in the inner cavity 5. The physician's left hand 12 is still controlling the epidural needle, and the physician's right hand 17 is singly controlling the dispenser 18 with the epidural catheter 1. Throughout the epidural injection procedure to this point, the epidural catheter 1 and its proximal end 20 have remained confined in the dispenser's sterile inner cavity. As the catheter is in a controlled, contained dispenser 18 the likelihood for contamination of the catheter is eliminated.

FIGURE 8 illustrates the early-staged withdrawal of the epidural needle 8 from the patient 14 once the distal catheter end 19 has been successfully placed into the patient's epidural space. The physician is still maintaining control of the epidural needle 8 with the thumb and index finger of the left hand 12; however, the physician has now pulled the epidural needle 8 from the patient, leaving the distal catheter end 19 in the patient. The epidural catheter 1 still traverses through the epidural needle bore, and the physician must completely pull the epidural catheter 1 through the epidural needle bore to totally remove the epidural needle. Through this process, the physician with the right hand, palm, and third, fourth, and fifth digits 17 is still maintaining control of the proximal end of the epidural catheter 20 inside the inner cavity 5 of the epidural catheter dispenser 18. FIGURE 8 illustrates that during this procedure, most of the epidural catheter 1 has been extracted from the inner cavity 5 of the dispenser through the dispenser aperture defined by the dispenser's distal end piece 4.

FIGURE 9 illustrates the continued removal of the epidural needle 8 from the patient 14. In traditional epidural injection procedure, the physician must contend with contamination of the proximal catheter end during the epidural needle removal process. In contrast, the physician utilizing the preferred embodiment of the current invention's dispenser 18 can withdraw the epidural needle 8 and pull the epidural catheter 1 through the epidural needle's bore with one hand, thereby keeping the catheter inside the dispenser's inner cavity and preventing catheter contamination. In this illustration, the physician is still utilizing the right hand 17 controlling the epidural catheter dispenser system 18 with righthand palm and third, fourth and fifth digits. Simultaneously, the physician's righthand thumb and index finger, or alternatively the right index finger and third digit (not illustrated), grasps the proximal handle on the epidural needle 10. The physician's left hand 12 has now moved to grasp the distal catheter end 19 close to the patient 14 to keep the epidural catheter 1 positioned in the patient. Thus, by firmly gripping the distal catheter end 19 next to the patient 14 while simultaneously pulling back toward the physician with the right hand 17 controlling the dispenser 18 and the epidural needle 8, the physician will extract the remaining epidural catheter 1 from the dispenser's inner cavity 5. By pulling the epidural catheter 1 through the dispenser aperture in the distal end piece 4, and through the epidural needle's bore in one motion, the physician is maintaining the sterility of the epidural catheter 1 especially the proximal catheter end 20 through the epidural needle 8 removal procedure. Throughout the entire epidural needle removal, the proximal catheter end 20 has remained positioned in the dispenser's sterile inner cavity, eliminating all likelihood of catheter contamination.

FIGURE 10 illustrates the completed epidural catheter 1 placement in the patient 14 and the complete removal of the epidural needle 8 from the patient 14. As illustrated, the epidural catheter 8 has been placed in the patient 14 with the distal catheter end 19 in the patient's epidural space and the proximal catheter end 20 controlled by the physician's left hand 12 ready to receive medication. The epidural catheter has been completely extracted from the dispenser 18 and the dispenser's inner cavity 5. The epidural catheter has also completely traversed through the epidural needle's central bore. Having completed the epidural catheter placement procedure, the physician's right hand 17 continues to hold the epidural catheter dispenser system 18 in the right-hand palm and

1 third, fourth and fifth digits 17 while also simultaneously holding the epidural needle
2 handle 10 in the righthand thumb and index finger. The physician can now discard the
3 dispenser and epidural needle, freeing up the right hand to administer medication through
4 the sterile proximal epidural catheter end 20.

5 In combination, FIGURES 4 through 10 illustrate that the epidural catheter is
6 placed in the patient's epidural space in a controlled and contained manner during the
7 entire sequence of the epidural injection procedure. Because the current invention's
8 epidural catheter dispenser system maintains the epidural catheter's sterility while
9 containing the proximal catheter end in the dispenser's sterile inner cavity and because
10 the only exposed portion of the epidural catheter is the distal catheter end – which the
11 physician is controlling during the catheter's placement into the epidural needle bore –
12 the preferred embodiment of the current invention eliminates the likelihood of catheter
13 contamination. As the probability of catheter contamination is dramatically reduced by
14 the current invention, correspondingly, the chance for patient infection from an epidural
15 procedure is also dramatically reduced.